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JC821 U.S. PTO

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Chris Zerby and Jay A. Warren

Title: LEAD HAVING VARYING STIFFNESS AND METHOD OF MANUFACTURING THEREOF

Attorney Docket No.: 279.246US1

PATENT APPLICATION TRANSMITTAL

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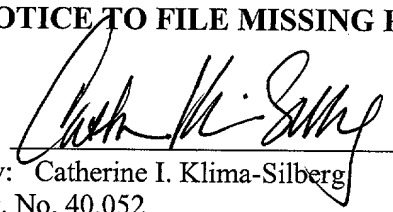
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TOTAL CLAIMS	42 - 20 =	22	x 18 =	\$396.00
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"Express Mail" mailing label number: EL618436248US

Date of Deposit: August 1, 2000

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LEAD HAVING VARYING STIFFNESS AND METHOD OF MANUFACTURING THEREOF

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Technical Field

The present invention relates generally to leads for conducting electrical
signals to and from the heart. More particularly, it pertains to a lead having
10 varying stiffness.

Background

Leads implanted in or about the heart have been used to reverse certain life
threatening arrhythmias, or to stimulate contraction of the heart. Electrical energy
15 is applied to the heart via the leads to return the heart to normal rhythm. Leads
have also been used to sense in the atrium or ventricle of the heart and to deliver
pacing pulses to the atrium or ventricle. Technically, the pacemaker or the
automatic implantable cardioverter defibrillator receives signals from the lead and
interprets them. The same lead used to sense the condition is sometimes also used
20 in the process of delivering a corrective pulse or signal from the pulse generator of
the pacemaker.

Cardiac pacing may be performed by the transvenous method or by leads
implanted directly onto the ventricular epicardium. Most commonly, permanent
transvenous pacing is performed using a lead positioned within one or more
25 chambers of the heart. The lead may also be positioned in both chambers,
depending on the lead, as when a lead passes through the atrium to the ventricle.
Electrodes of the lead may be positioned within the atrium or the ventricle of the
heart. For other applications, the lead may be positioned in cardiac veins.

Positioning an electrode disposed on a distal end of a lead within a vein
30 presents additional challenges in maintaining the lead in a fixed position since the

distal end of the lead does not abut a surface. These challenges also may result in poor pacing and sensing capabilities of the electrode.

Therefore, there is a need for a lead having an electrode for positioning within passages such as cardiac veins, that allows for fixation therein. In addition,
5 what is needed is a lead which can be sufficiently positioned within a patient.

Summary

An apparatus includes a lead body which extends from a proximal end to a
10 distal end and has an intermediate portion therebetween. In addition, the lead body includes two or more individually insulated conductors. At least one of the conductors is a first conductor which traverses along less than an entire length of the lead body. A second conductor traverses from the proximal end to the distal end of the lead body. For instance, the lead body has four conductors disposed at
15 the proximal end of the lead body, and two conductors disposed at the distal end of the lead body. The apparatus further includes an electrode assembly including at least one electrode electrically coupled with at least one of the conductors.

Optionally, the first conductor extends from the distal end of the lead body to the intermediate portion of the lead body. In one embodiment, the first
20 conductor is comprised of a first material, and the second conductor is comprised of a second material, where the first material has a different stiffness and/or electrical property than the second material. Optionally, the first material or the second material comprises conductive polymer material or is formed of material having heat setting capabilities.

25 In another embodiment, the lead body includes a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and the third sections. The location of the conductors is varied by embodiment. For instance, the first conductor is disposed only in the first and second sections. In another option, the first conductor is disposed only in the first

and third sections. In yet another option, the first conductor is disposed only in the second and third sections. For each of these options, a variation includes having the first conductor comprised of material of a greater stiffness than the second conductor. In another embodiment, the electrode is disposed between the second
5 and the third sections.

An apparatus includes a lead body which extends from a proximal end to a distal end and has an intermediate portion therebetween. In addition, the lead body includes two or more individually insulated conductors. At least one of the conductors is a first conductor which is formed of a first material. A second
10 conductor is formed of a second material, which has a different stiffness and/or electrical property than the first material. For instance, the first material comprises MP35N and the second material comprises Pt/Ta.

The apparatus further includes an electrode assembly including at least one electrode electrically coupled with at least one of the conductors. In one
15 embodiment, one of the conductors electrically and mechanically terminates at the electrode assembly. Optionally, the first conductor traverses along less than an entire length of the lead body and the second conductor traverses from the proximal end to the distal end of the lead body.

Further options which can be combined with that above are described
20 below. For instance, one or more conductors includes two or more filars. In another option, the lead body includes a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and the third sections, where the first conductor is disposed in different sections depending on the embodiment. For example, the first conductor is disposed only
25 in the second and third sections, or four conductors are disposed at the proximal end of the lead body, and two conductors are disposed at the distal end of the lead body.

A method includes varying the stiffness of a coiled conductor assembly including winding a plurality of conductors to form the coiled conductor assembly,

and pulling at least one loop of a first conductor away from the coiled conductor assembly. In addition, the method optionally includes crimping the at least one loop and/or electrically coupling the first conductor to an electrode. Optionally, the first conductor is electrically terminated at the electrode. Additional optional
5 steps includes spinning a mandrel and forming the coiled conductor assembly therein, and pulling the loop includes stopping the mandrel. One or more second loops of a second conductor are also pulled, wherein pulling one or more second loops of a second conductor involves pulling a second conductor having a different material than the first conductor.

10 A method includes modifying a stiffness of a lead extending from a proximal end to a distal end, where the lead includes two or more conductors. Modifying the stiffness includes forming insulation on the two or more conductors, winding the two or more conductors and dropping out one or more
15 more conductors at an intermediate portion of the lead. Optionally, winding the two or more conductors includes winding two or more conductors each having a different material. An additional optional step includes pulling a loop of at least one conductor during the winding. The method further includes, in another embodiment, crimping and swaging the loop of conductor. Optionally, the method further includes electrically coupling the conductor with an electrode of the lead.

20 The lead assembly provides several benefits including a lead which has varying stiffness throughout the lead. Furthermore, the conductors and/or portions of the lead formed of materials having increased stiffness will assist in retaining and/or positioning the lead assembly in a desired location of the heart or vein or artery. The lead assembly is also beneficial in applications where the electrode is
25 disposed in a larger vein or artery where it is otherwise difficult to position and/or maintain an electrode against the wall of the surrounding tissue.

These and other embodiments, aspects, advantages, and features of the present invention will be set forth in part in the description which follows, and in part will become apparent to those skilled in the art by reference to the following

description of the invention and referenced drawings or by practice of the invention. The aspects, advantages, and features of the invention are realized and attained by means of the instrumentalities, procedures, and combinations particularly pointed out in the appended claims and their equivalents.

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Brief Description of the Drawings

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|----|-----------|--|
| | Figure 1 | is a cross-section view illustrating a lead assembly constructed in accordance with one embodiment. |
| 10 | Figure 2A | is a cross-section view illustrating a conductor constructed in accordance with one embodiment. |
| | Figure 2B | is a cross-section view illustrating a conductor constructed in accordance with one embodiment. |
| | Figure 3 | is a cross-section view illustrating a lead assembly constructed in accordance with one embodiment. |
| 15 | Figure 4 | is a cross-section view illustrating a lead assembly constructed in accordance with one embodiment. |
| | Figure 5 | is a cross-section view illustrating a lead assembly constructed in accordance with one embodiment. |
| 20 | Figure 6 | is a cross-section view illustrating a lead assembly constructed in accordance with one embodiment. |
| | Figure 7 | is an elevational view illustrating a lead assembly constructed in accordance with one embodiment. |
| | Figure 8 | is an elevational view illustrating a lead assembly constructed in accordance with one embodiment. |
| 25 | Figure 9 | is a perspective view illustrating a portion of a conductor assembly constructed in accordance with one embodiment. |
| | Figure 10 | is an elevational view illustrating a portion of a conductor assembly constructed in accordance with one embodiment. |

- Figure 11 is an elevational view illustrating a portion of a conductor assembly constructed in accordance with one embodiment.
- Figure 12 is an elevational view illustrating a portion of a conductor assembly constructed in accordance with one embodiment.
- 5 Figure 13 is an elevational view illustrating a portion of a conductor assembly constructed in accordance with one embodiment.
- Figure 14 is a cross-section view illustrating a portion of a lead assembly constructed in accordance with one embodiment.
- Figure 15 is a cross-section view illustrating a lead assembly constructed in accordance with one embodiment.
- 10 Figure 16 is a cross-section view illustrating a lead assembly constructed in accordance with one embodiment.

15 **Detailed Description**

In the following detailed description, reference is made to the accompanying drawings which form a part hereof, and in which is shown by way of illustration specific embodiments in which the invention may be practiced. These embodiments are described in sufficient detail to enable those skilled in the art to practice the invention, and it is to be understood that other embodiments may be utilized and that structural changes may be made without departing from the scope of the present invention. Therefore, the following detailed description is not to be taken in a limiting sense, and the scope of the present invention is defined by the appended claims and their equivalents.

- 20 Figure 1 illustrates a lead 100 for delivering electrical pulses to stimulate a heart and/or for receiving electrical pulses to monitor the heart. The lead 100 includes a lead body 115 which is covered by a biocompatible insulating material. Silicone rubber or other insulating material is used for covering the lead body 115. The lead 100 has a distal end 102 adapted for implant within a body, for

instance within a vein, and a proximal end 104. The proximal end 104 has a connector terminal 105 which electrically connects the various electrodes and conductors within the lead 100 to a pulse generator and signal sensor. The terminal connector 105 provides for the electrical connection between the lead
5 100 and the pulse generator. The pulse generator contains electronics to sense various electrical signals of the heart and also to produce current pulses for delivery to the heart.

Disposed between the distal end 102 and the proximal end 104 of the lead 100 is an intermediate portion, as will be further described below. The lead 100
10 includes at least one electrode 120 disposed between the distal end 102 and the proximal end 104. At least one conductor 130 (Figure 2) is electrically coupled with the at least one electrode 120. The at least one conductor 130 comprises a coiled conductor 130 which includes one or more filars 132. Figure 2A illustrates the at least one conductor 130 with one filar 132. In one embodiment, as shown
15 in Figure 2B, the at least one conductor 130 has three filars 134. Other options include a conductor which is a solid wire, or a conductor which has braided strands of wire or filars. The at least one conductor 130 includes insulation 136 thereover. Suitable materials for insulation include, but are not limited to, ETFE, silicone, polyurethane, or other insulating material. Optionally, the lead 100
20 includes two or more conductors 130. It should be noted, however, that each conductor 130 need not be electrically coupled with the at least one electrode 120.

Referring again to Figure 1, the lead 100 is defined in part by a first intermediate portion 108 and a second intermediate portion 110. The first intermediate portion 108 is more near the proximal end 104 of the lead 100 than
25 the second intermediate portion 110, such that the lead 100 is defined by multiple sections. A first section 180 is disposed between the proximal end 104 and the first intermediate portion 108, a second section 182 is disposed between the first intermediate portion 108 and the second intermediate portion 110. A third section

184 of the lead 100 is disposed between the second intermediate portion 110 and the distal end 102.

5 A first conductor 140 and a second conductor 142 extend from the proximal end 104 to the distal end 102 of the lead 100. A third conductor 144 and a fourth conductor 146 extend from the proximal end 104 to the second intermediate portion 110. As a result, the first and second conductors 140, 142 are disposed in the first, second, and third sections 180, 182, 184 of the lead 100. The third and fourth conductors 144, 146 are disposed in the first and second sections, 180, 182. Optionally, an electrode 120 is disposed between the first and
10 second sections 180, 182, and/or the electrode 120 is disposed between the second and third sections 182, 184. One or more of the first, second, third, or fourth conductors 140, 142, 144, 146 optionally electrically terminate at the electrode 120.

Figure 3 illustrates an alternative for the lead 100, where the first
15 conductor 140 and the second conductor 142 extend from the proximal end 104 to the distal end 102 of the lead 100. The third conductor 144 extends from a second intermediate portion 110 to the distal end 102 of the lead 100. Optionally, the third conductor 144 extends from the proximal end 104 to a first intermediate portion 108, terminating at the first intermediate portion 108. In another
20 alternative, a fourth conductor 146 extends from the second intermediate portion 110 to the distal end 102 of the lead 100, and extends from the proximal end 104 to the first intermediate portion 108. As a result, the first and second conductors are disposed in the first, second, and third sections 180, 182, 184 of the lead 100. The third and fourth conductors 144, 146 are disposed in the first and third
25 sections, 180, 184. Optionally, a first electrode 150 is disposed between the first and second sections 180, 182 where third and fourth conductors 144, 146 mechanically and electrically terminate at the first electrode 150. In another option, a second electrode 152 is disposed between the second and third sections

182, 184, and the third and fourth conductors 144, 146 mechanically and electrically terminate at the second electrode 152.

Figure 4 illustrates another alternative for the lead 100, where the first conductor 140 and the second conductor 142 extend from the proximal end 104 to the distal end 102 of the lead 100. The third conductor 144 and the fourth conductor 146 extend from the first intermediate portion 108 to the distal end 102 of the lead 100. As a result, the first and second conductors are disposed in the first, second, and third sections 180, 182, 184 of the lead 100. The third and fourth conductors 144, 146 are disposed in the second and third sections, 182, 184. Optionally, the first electrode 150 is disposed between the first and second sections 180, 182 where third and fourth conductors mechanically terminate at the first electrode 150. In another option, a second electrode 152 is disposed between the second and third sections 182, 184, where the third and fourth conductors 144, 146 optionally electrically terminate at the second electrode.

Referring to Figure 5, another alternative of the lead 100 is shown which is defined in part by a first section 190 and a second section 192. The first section 190 is more near the proximal end 104 of the lead 100 than the second section 192 such that the lead 100 is defined by multiple sections. Optionally, the lead 100 includes a first electrode 194 and/or a second electrode 196, where the first electrode 194 is disposed between the first section 190 and the second section 192, and the second electrode 196 is disposed in the second section 192.

A first conductor 140 and a second conductor 142 extend from the proximal end 104 to the distal end 102 of the lead 100. A third conductor 144 and a fourth conductor 146 extend along the first section 190. The third conductor 144 and the fourth conductor 146 electrically and mechanically terminate at the optional first electrode 194. As a result, the first and second conductors 140, 142 are disposed in the first and second sections 190, 192 of the lead 100. The third and fourth conductors 144, 146 are disposed in the first section 190 of the lead 100.

Figure 6 illustrates another alternative of the lead 100. A first conductor 140 and a second conductor 142 extend from the proximal end 104 to the distal end 102 of the lead 100. A third conductor 144 and a fourth conductor 146 extend along only the second section 192. The third conductor 144 and the fourth conductor 146 electrically and mechanically terminate at the optional first electrode 194. As a result, the first and second conductors 140, 142 are disposed in the first and second sections 190, 192 of the lead 100. The third and fourth conductors 144, 146 are disposed only in the first section 190 of the lead 100.

Figures 15 and 16 illustrate other options for a lead 20. Similar to that above, the lead 20 extends from a proximal end 22 to a distal end 24. The lead 20 includes four sections 32, 34, 36, 38, where the fourth section 38 is adjacent to the distal end 24. Optionally disposed between the sections is one or more electrodes. For instance, a first electrode 80 is disposed between the first section 32 and the second section 34, a second electrode 82 is disposed between the second section 34 and the third section 36, and a third electrode 84 is disposed between the third section 36 and the fourth section 38. It is possible to have more electrodes or fewer electrodes than the first, second, and third electrodes 80, 82, 84.

Referring to Figure 15, a first conductor 40 extends from the proximal end 22 to the distal end 24 of the lead 20. A second conductor 42 extends from the proximal end 22 to the third electrode 84. A third conductor 44 extends from the proximal end 22 to the second electrode 82. A fourth conductor 46 extends from the proximal end 22 to the first electrode 80. Optionally, instead of any of the above mentioned electrodes, the conductors merely terminate at a location of the electrode, and the electrode is not included.

Referring to Figure 16, the first and second conductors 40, 42 extend from the proximal end 22 to the distal end 24 of the lead 20. The third conductor 44 extends from the proximal end 22 to the third electrode 84. The fourth conductor 46 extends from the proximal end 22 to the second electrode 82. Optionally,

instead of any of the above mentioned electrodes, the conductors merely terminate at a location of the electrode, and the electrode is not included.

The conductors are formed, in one example, by winding. The materials used for each conductor are optionally varied, such that the stiffness of the material and the conductor are varied. For instance, of the above discussed lead 100, the first conductor 140 and the second conductor 142 are formed of a first material and the third conductor 144 and the fourth conductor 146 are formed of a second material. Optionally, the first material has a different stiffness than the second material. Examples of materials which are used to form any of the conductors include, but are not limited to, MP35N, Pt/Ir composites, which are relatively stiff materials. Less stiff materials include a composite of MP35N with a Ta core or a composite of MP35N with a Ag core. Relatively lesser stiff materials are also used including, but not limited to, Pt clad Ta, Pt clad Ti, or Ti. In another alternative, a conductive polymer is used to form the conductor.

In another option, materials having different electrical properties are used to form the conductors. For instance, at least one conductor is formed of a material having a first electrical property, and at least another conductor is formed of a material having a second electrical property. Having conductors formed of two different materials of differing electrical properties results in electrodes of the lead 100 to exhibit different electrical properties, for example, impedance. In yet another option, a material having heat setting properties is used to form one or more of the conductors of the lead 100 such that desired shapes for fixation and electrode contact can be achieved. It should be noted that any of the above discussed materials can be used in any of the above and below discussed embodiments. Other materials which will affect the properties of the lead 100 can also be used.

As an example of using different materials, the lead includes two conductors which extend the entire length of the lead, and are formed of Pt/Ta. Two other conductors extend less than the entire length of the lead and are formed

of MP35N, which is more stiff than the Pt/Ta. The less stiff material which extends to the distal end 102 of the lead 100 allows for suitable flexibility for chronic placement of the lead 100 within a vein of a patient. In addition, the material also provides a gentle bias in the area of the electrode such that sufficient force is provided for tissue contact by the electrode. For instance, as shown in Figures 7 and 8, the lead 100 and the coiled conductors therein is formed into a shape having a two 178 or three 179 dimensional bias. The lead 100 having a bias allows for tissue contact between an electrode 181 and a wall of a vein 177. It should be noted that the lead 100 is not limited to having four conductors and the number of conductors and the materials used for each can be modified.

As discussed above, the lead 100 includes a first conductor and a second conductor, which, in one embodiment, are formed of two different materials. Figure 9 illustrates one example of a winding configuration for a portion of a conductor assembly 200 for use in the lead 100 which includes a first conductor 240 and a second conductor 242 each formed of a different material. Optionally, a third 244 and a fourth 246 conductor are included. For instance, the first conductor 240 and the third conductor 244 are formed of MP35N and the second 242 and the fourth 246 conductor are formed of Pt/Ta. The first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 are each wound together, and transition to the second conductor 242 and the fourth conductor 246, as shown in Figure 9, and as further described below. It should be noted that the conductor assembly 200 can be used in any of the above or below described embodiments, and that other winding configurations are possible.

Figure 10 illustrates another example of how to form the conductor assembly 200. The conductor assembly 200 is wound, for example, using a mandrel. The conductor assembly 200 is wound with four conductors, including the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246, which are each wound from a proximal end 204 to a distal end

202 of the conductor assembly 200. In one embodiment, two or more different materials are used for forming the conductor assembly 200. In another embodiment, one or more of the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 are electrically terminated at various
5 locations 250 along the conductor assembly 200. Optionally, during the winding of the coil assembly 200, one or more of the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 is dropped out of the winding, for instance, at a location of an electrode.

Figure 11 illustrates another example of how to form the conductor
10 assembly 200. The conductor assembly 200 is wound, for example, using a mandrel. The conductor assembly 200 is wound with four individually insulated conductors, including the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246. In one embodiment, two or more different conductor materials are used for forming the conductor assembly 200.
15 During the winding process, one or more of the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 are pulled out of the winding. For example, at a first location 230, the first conductor 240 is pulled from the coil 201, and yet the first conductor 240 continues being wound past the first location 230. The first conductor 240 is pulled from the coil 201 at a second
20 location 232, and the first conductor 240 continues being wound past the second location 232. At a third location 234, the second conductor 242 is pulled from the coil 201 and the second conductor 242 continues being wound past the third location 234. Rather than terminating the filars, the conductors are reintroduced into the winding, either to another location of the coil assembly 200, such as at an
25 electrode, or to the distal end of the coil assembly.

Optionally, one or more of the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 are electrically terminated at various locations 250 along the conductor assembly. Advantageously, pulling the loop allows for the conductor to be electrically coupled with the electrode, but yet

optionally allows the electrical connection to be thereafter terminated as the conductor extends to the distal end of the lead 100. Another benefit provided is that a single conductor can be coupled with more than one electrode, providing more options for the lead designer and the physician.

5 Figure 12 illustrates another example of how to form the conductor assembly 200. The conductor assembly 200 is wound, for example, using a mandrel. The conductor assembly 200 is wound with, for example, four conductors, including the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 to form the coil 201. It should be noted
10 that in this and the above and below discussed embodiments, the number of conductors can be changed, yet are considered within the scope of the application. In one embodiment, two or more different materials are used for forming the conductor assembly 200.

 During the winding process, two or more of the first conductor 240,
15 second conductor 242, third conductor 244, and fourth conductor 246 are pulled out of the winding. The mandrel is optionally stopped while the conductors are pulled out of the winding, and then restarted to continue the winding process. For example, at a first location 230, the first conductor 240 and the second conductor 242 are each pulled from the coil 201, and yet the first conductor 240 and/or the
20 second conductor 242 continues being wound past the first location 230. The second conductor 242 is pulled at the same location as the first conductor 240, such that the second conductor 242 is adjacent to the first conductor 240. The first conductor 240 and the second conductor 242 are pulled from the coil 201 at a second location 232, and the first conductor 240 and/or the second conductor 242
25 continues being wound past the second location 232.

 At a third location 234, the third conductor 244 and the fourth conductor 246 are pulled from the coil 201 and the third conductor 244 and/or the fourth conductor 246 continues being wound past the third location 234. Rather than mechanically terminating the filars, the conductors are reintroduced into the

winding, either to another location of the coil assembly 200, such as at an electrode, or to the distal end of the coil assembly. Optionally, one or more of the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 are electrically terminated at various locations 250 along the conductor assembly.

Figure 13 illustrates another example of how to form the conductor assembly 200. The conductor assembly 200 is wound, for example, using a mandrel. The conductor assembly 200 is wound with, for example, four conductors, including the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 to form the coil 201. In one embodiment, two or more different materials are used for forming the conductor assembly 200.

During the winding process, one or more of the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 are pulled out of the winding at one or more locations, and two or more of the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 are pulled out of the winding at one or more locations. To pull the conductors, the mandrel is optionally stopped while the conductors are pulled out of the winding, and then restarted to continue the winding process.

At a first location 230, for example, the first conductor 240 is pulled from the coil 201, and yet the first conductor 240 continues being wound past the first location 230. At a second location 232, the second conductor 242 is pulled from the coil 201, and yet the second conductor 242 continues being wound past the second location 232. At a third location 234, the third conductor 244 and the fourth conductor 246 are pulled from the coil 201 and the third conductor 244 and/or the fourth conductor 246 continues being wound past the third location 234. The first conductor 240 and the second conductor 242 are pulled from the coil 201 at a fourth location 236, and the first conductor 240 and/or the second conductor 242 continues being wound past the fourth location 236. The second

conductor 242 is pulled at the same location as the first conductor 240, such that the second conductor 242 is adjacent to the first conductor 240.

For any of the conductors, rather than mechanically terminating the filars, the conductors are optionally reintroduced into the winding, either to another
5 location of the coil assembly 200, such as at an electrode, or to the distal end of the coil assembly. Optionally, one or more of the first conductor 240, second conductor 242, third conductor 244, and fourth conductor 246 are electrically terminated at various locations along the conductor assembly.

Figure 14 illustrates a lead 300 with a conductor assembly 320. The
10 conductor assembly 320 includes, but is not limited to, those which are formed with the above methods, or above discussed structures. The conductor assembly 320 includes one or more conductors 310. One or more of the conductors 310 is electrically coupled with at least one electrode 350. Optionally, one or more of the conductors is mechanically and/or electrically terminated at an intermediate
15 portion 303 of the lead 300. For example, a conductor is pulled during the winding process. The conductor is then crimped, swaged, welded or otherwise mechanically and electrically coupled with the electrode 350. It should be noted that other methods, or combinations of methods, of mechanically and/or electrically coupling the conductor with the electrode 350 would be suitable as
20 well.

The above-described lead assembly provides several benefits including a lead which has varying stiffness throughout the lead. Furthermore, the conductors and/or portions of the lead formed of materials having increased stiffness will assist in retaining and/or positioning the lead assembly in a desired location of the
25 heart or vein or artery. The lead assembly is also beneficial in applications where the electrode is disposed in a larger vein or artery where it is otherwise difficult to position and/or maintain an electrode against the wall of the surrounding tissue.

It is to be understood that the above description is intended to be illustrative, and not restrictive. Although the use of the lead has been described

for use in a cardiac pacing system, the lead could be applied to other types of body stimulating systems or the embodiments could be used in the application of other medical devices. Furthermore, it should be noted that the above described embodiments include windings which are right hand wound, and windings which
5 are left hand wound. Many other embodiments and applications will be apparent to those of skill in the art upon reviewing the above description. It should be noted that embodiments discussed in different portions of the description or referred to in different drawings can be combined to form additional embodiments of the present invention. The scope of the invention should, therefore, be
10 determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

What is claimed is:

1. An apparatus comprising:
 - a lead body extending from a proximal end to a distal end and having an intermediate portion therebetween, the lead body including two or more individually insulated conductors disposed therein;
 - at least one conductor including a first conductor and a second conductor, the first conductor traversing along less than an entire length of the lead body;
 - the second conductor traversing from the proximal end to the distal end of the lead body; and
 - an electrode assembly including at least one electrode electrically coupled with at least one conductor.
2. The apparatus as recited in claim 1, wherein at least the first conductor extends from the distal end of the lead body to the intermediate portion.
3. The apparatus as recited in claim 1, wherein one or more conductors each includes two or more filars.
4. The apparatus as recited in claim 1, wherein at least the first conductor is comprised of a first material, and at least the second conductor is comprised of a second material, where the first material has a different stiffness than the second material.
5. The apparatus as recited in claim 4, wherein the first material or the second material comprises conductive polymer material.
6. The apparatus as recited in claim 1, wherein at least the first conductor is comprised of a first material, and at least the second conductor is comprised of a

second material, where the first material has different electrical properties than the second material.

7. The apparatus as recited in claim 1, wherein the lead body has four conductors disposed at the proximal end of the lead body, and two conductors disposed at the distal end of the lead body.

8. The apparatus as recited in claim 1, wherein at least one of the conductors is formed of material having heat setting capabilities.

9. The apparatus as recited in claim 1, wherein the conductors and the lead body have a two or three dimensional bias.

10. The apparatus as recited in claim 1, wherein the lead body includes a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and the third sections, where the first conductor is disposed only in the first and second sections.

11. The apparatus as recited in claim 1, wherein the lead body includes a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and the third sections, where the first conductor is disposed only in the first and third sections.

12. The apparatus as recited in claim 1, wherein the lead body includes a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and the third sections, where the first conductor is disposed only in the second and third sections.

13. The apparatus as recited in claim 12, wherein the first conductor is comprised of material having a greater stiffness than the second conductor.
14. The apparatus as recited in claim 12, wherein the at least one electrode is disposed between the second and the third sections.
15. The apparatus as recited in claim 1, wherein the first conductor electrically and/or mechanically terminates at the electrode assembly.
16. An apparatus comprising:
a lead body extending from a proximal end to a distal end and having an intermediate portion therebetween, the lead body including two or more individually insulated conductors disposed therein;
the insulated conductors including a first conductor and a second conductor, the first conductor comprised of a first material, and the second conductor comprised of a second material, where the first material has a different stiffness than the second material; and
an electrode assembly including at least one electrode electrically coupled with at least one conductor.
17. The apparatus as recited in claim 16, wherein at least one conductor traverses from the proximal end to the distal end, and at least one other conductor traverses along only a portion of the lead body.
18. The apparatus as recited in claim 17, wherein the at least one other conductor electrically and mechanically terminates at the electrode assembly.
19. The apparatus as recited in claim 16, wherein one or more conductors includes two or more filars.

20. The apparatus as recited in claim 16, wherein the first material and the second material have different electrical properties.
21. The apparatus as recited in claim 16, wherein the first material comprises MP35N.
22. The apparatus as recited in claim 21, wherein the second material comprises Pt/Ta.
23. The apparatus as recited in claim 22, wherein the lead body includes a first section near the distal end, a third section near the proximal end, and a second section disposed between the first and the third sections, where the first conductor is disposed only in the second and third sections.
24. The apparatus as recited in claim 16, wherein the lead body has four conductors disposed at the proximal end of the lead body, and two conductors disposed at the distal end of the lead body.
25. The apparatus as recited in claim 16, wherein at least one of the conductors is formed of material having heat setting capabilities.
26. The apparatus as recited in claim 16, wherein the conductors and the lead body have a two or three dimensional bias.
27. An apparatus comprising:
a lead body extending from a proximal end to a distal end and having an intermediate portion therebetween, the lead body including two or more individually insulated conductors disposed therein;

the insulated conductors including a first conductor and a second conductor, the first conductor traversing along less than an entire length of the lead body, the first conductor extending from the distal end of the lead body to the intermediate portion;

the second conductor traversing from the proximal end to the distal end of the lead body;

at least the first conductor is comprised of a first material, at least the second conductor is comprised of a second material, the first material having a different stiffness than the second material;

the lead body having four conductors disposed at the proximal end of the lead body, and two conductors disposed at the distal end of the lead body;
and

an electrode assembly including at least one electrode electrically coupled with at least one conductor, the first conductor electrically and/or mechanically terminating at the electrode assembly.

28. A method of varying the stiffness of a coiled conductor assembly, the method comprising:

winding a plurality of conductors to form the coiled conductor assembly
pulling at least one loop of a first conductor away from the coiled conductor assembly.

29. The method as recited in claim 28, further comprising crimping the at least one loop.

30. The method as recited in claim 29, further comprising electrically coupling the first conductor to an electrode.

31. The method as recited in claim 30, further comprising electrically terminating the first conductor at the electrode.
32. The method as recited in claim 28, further comprising spinning a mandrel and forming the coiled conductor assembly therein, and pulling the loop includes stopping the mandrel.
33. The method as recited in claim 28, further comprising pulling one or more second loops of a second conductor.
34. The method as recited in claim 28, further comprising pulling one or more second loops of a second conductor having a different material than the first conductor.
35. The method as recited in claim 33, wherein pulling one or more second loops is performed directly adjacent to the first loop.
36. The method as recited in claim 33, further comprising pulling one or more third loops of a third conductor.
37. The method as recited in claim 36, further comprising pulling one or more third loops of a fourth conductor.
38. A method of modifying a stiffness of a lead extending from a proximal end to a distal end, where the lead includes two or more conductors therein, the method comprising:
forming insulation on the two or more conductors; and
winding the two or more conductors and dropping out one or more conductors at an intermediate portion of the lead.

39. The method as recited in claim 38, wherein winding the two or more conductors includes winding two or more conductors each having a different material.

40. The method as recited in claim 38, further comprising pulling a loop of at least one conductor during the winding.

41. The method as recited in claim 40, further comprising crimping and swaging the loop of conductor.

42. The method as recited in claim 41, further comprising electrically coupling the conductor with an electrode of the lead.

LEAD HAVING VARYING STIFFNESS AND METHOD OF MANUFACTURING THEREOF

Abstract of the Disclosure

5 An apparatus includes a lead body extending from a proximal end to a
distal end and having an intermediate portion therebetween. The lead body
includes two or more individually insulated conductors, where a first conductor
traverses along less than an entire length of the lead body and a second conductor
traverses from the proximal end to the distal end of the lead body. Optionally, the
10 first conductor has a different material than the second conductor, for instance
having differing electrical properties and/or differing stiffnesses. A method
includes varying the stiffness of a coiled conductor assembly including winding a
plurality of conductors to form the coiled conductor assembly, and pulling at least
one loop of a first conductor away from the coiled conductor assembly.

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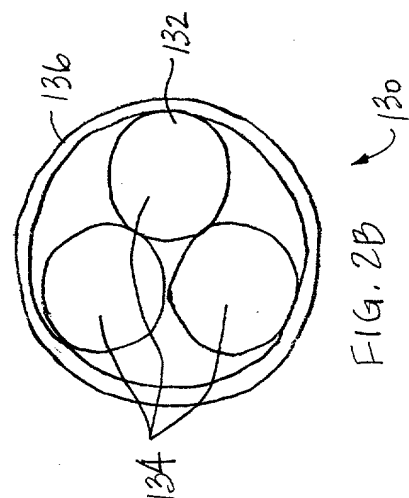
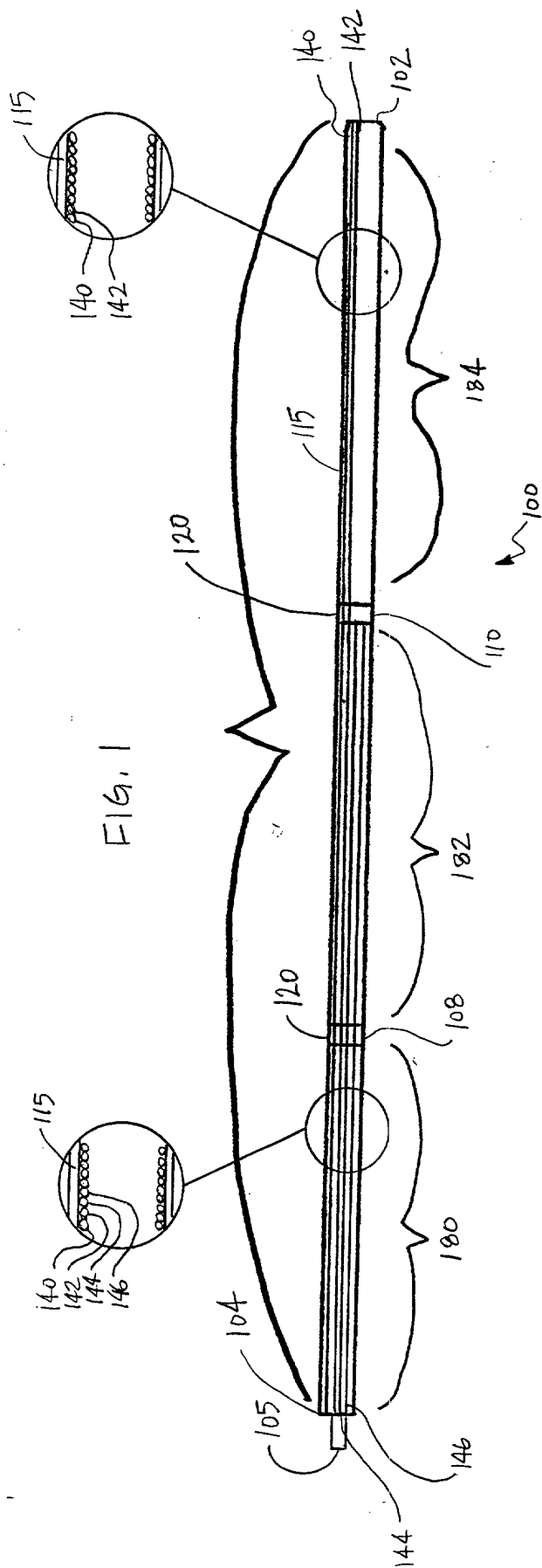


FIG. 2B

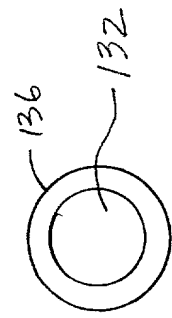


Fig. 2A

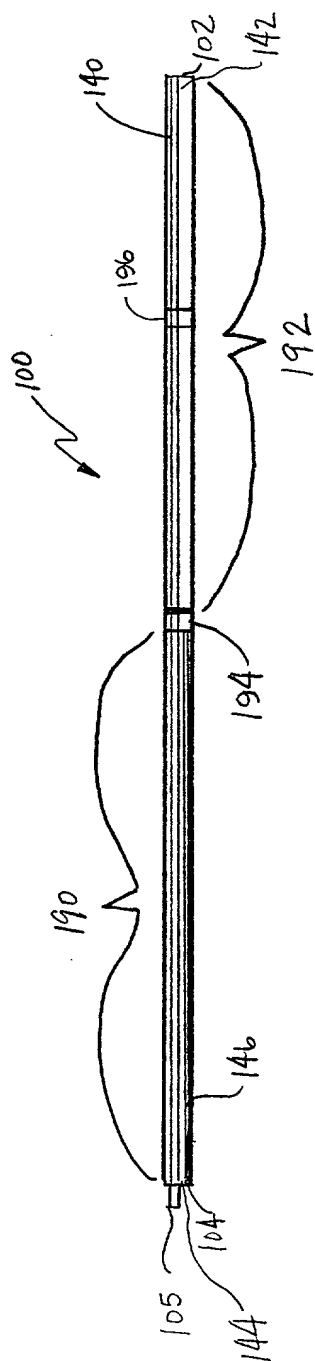


Fig. 5

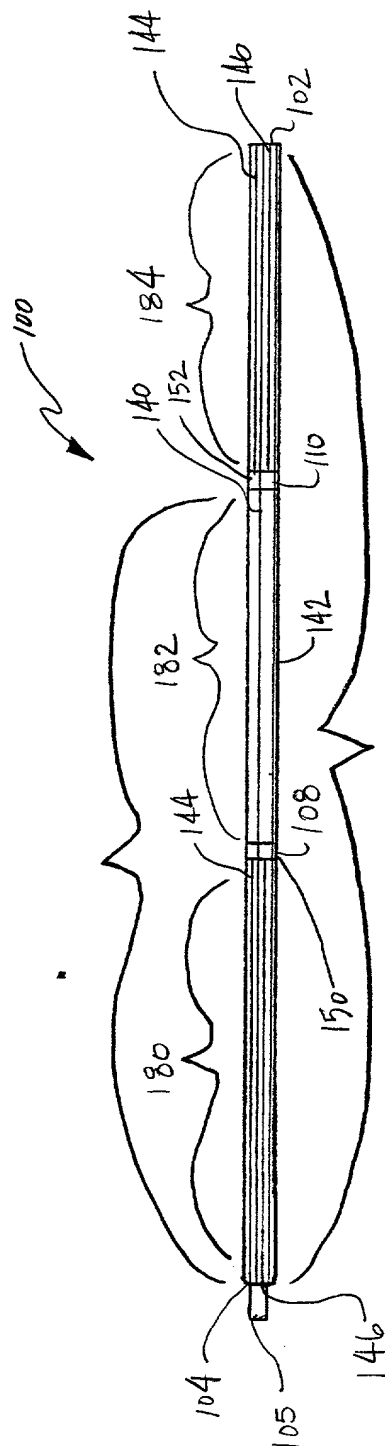


Fig. 3

1

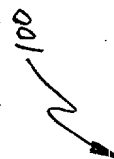


Fig. 4

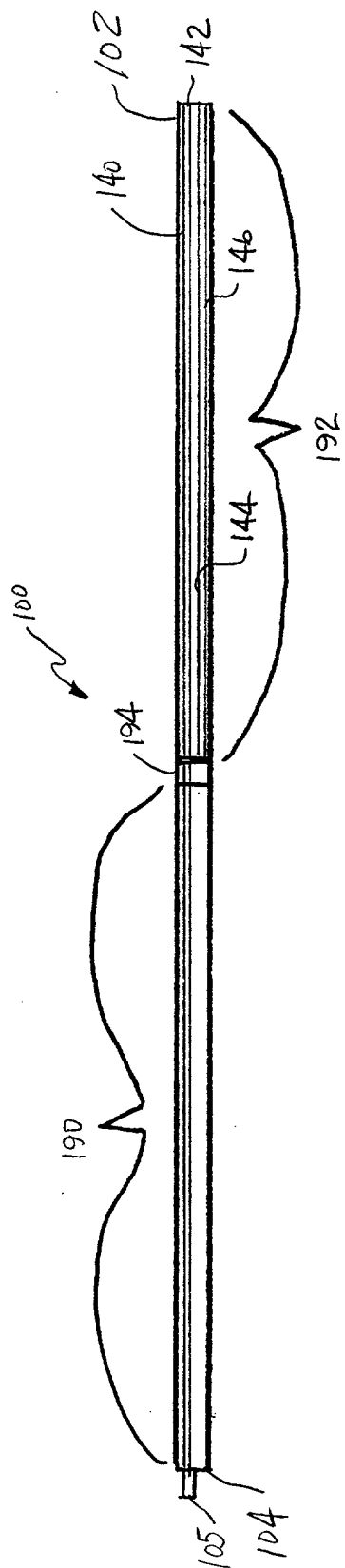


FIG. 6

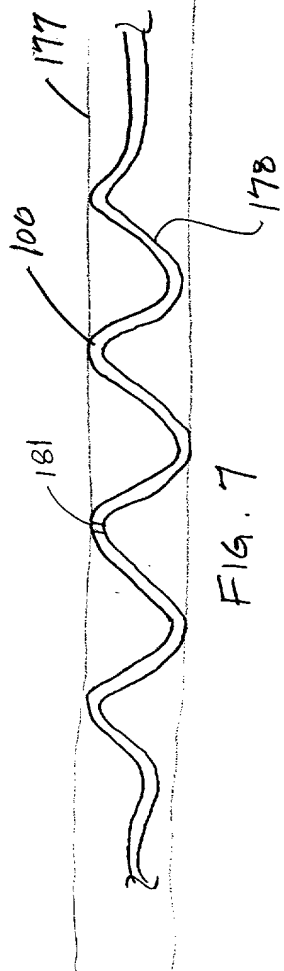


FIG. 7

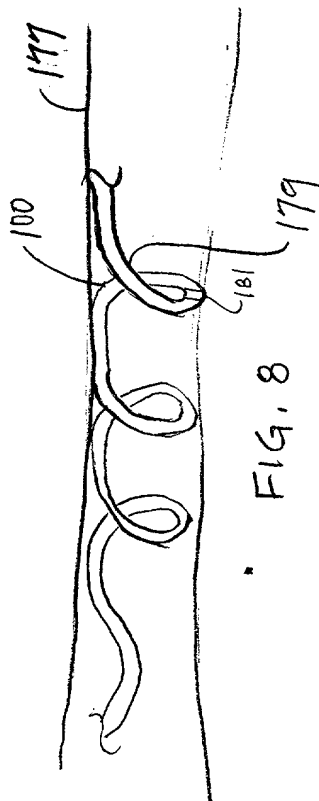


FIG. 8

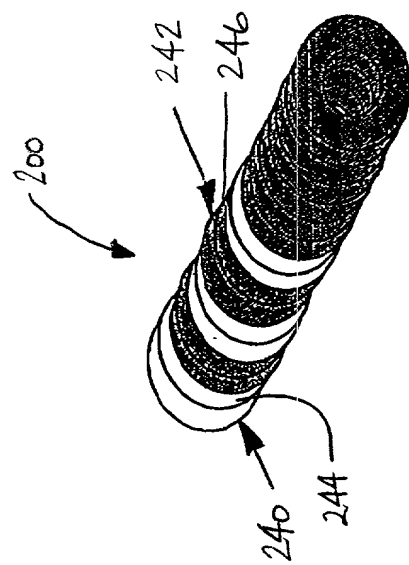
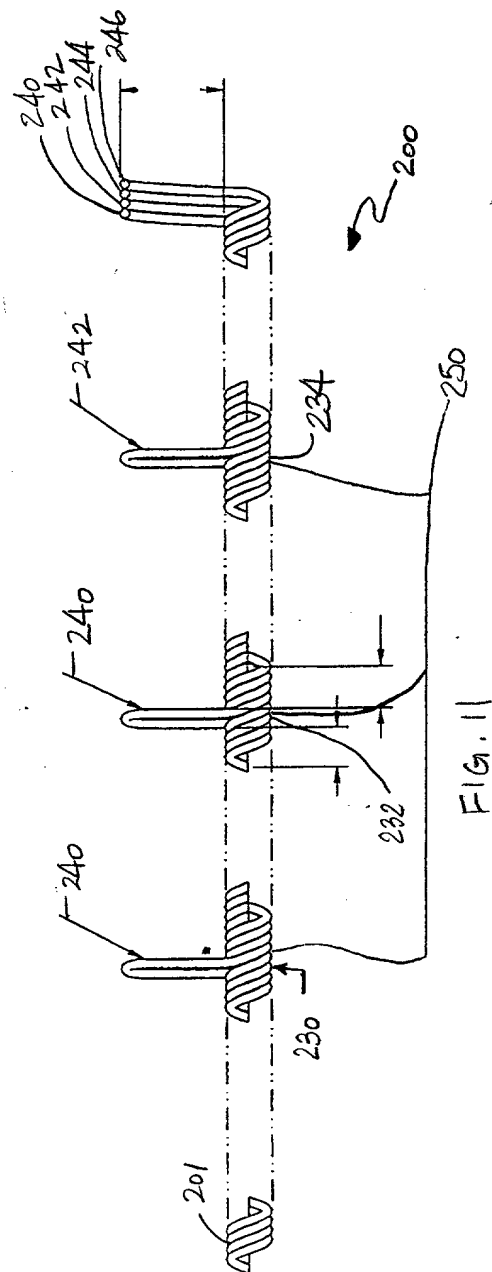
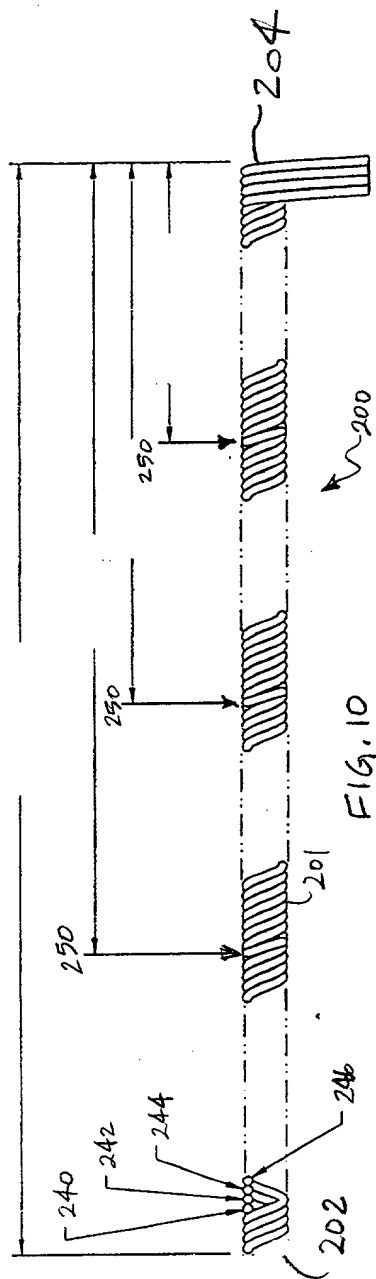
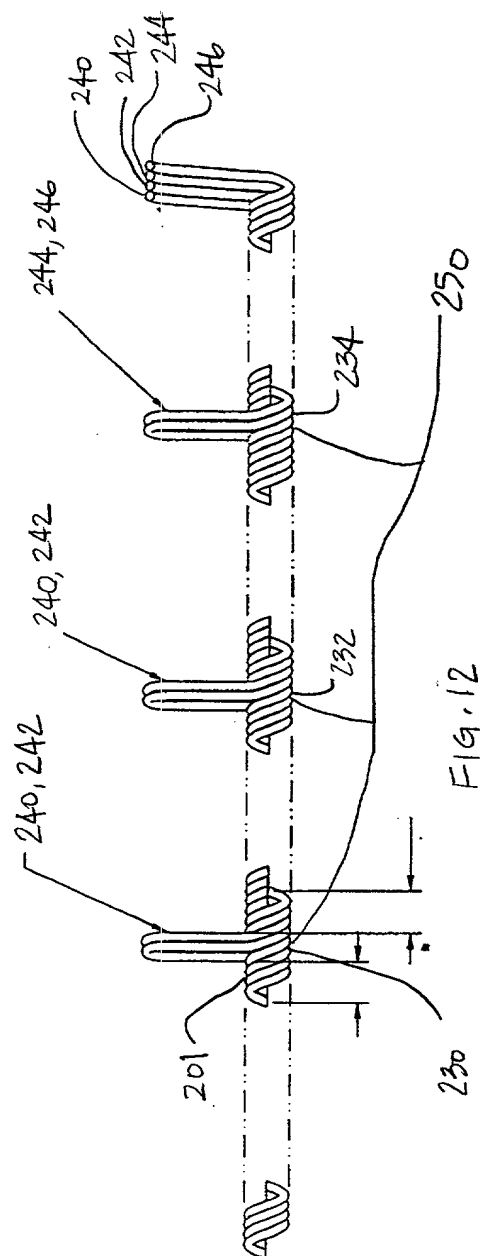


Fig. 9





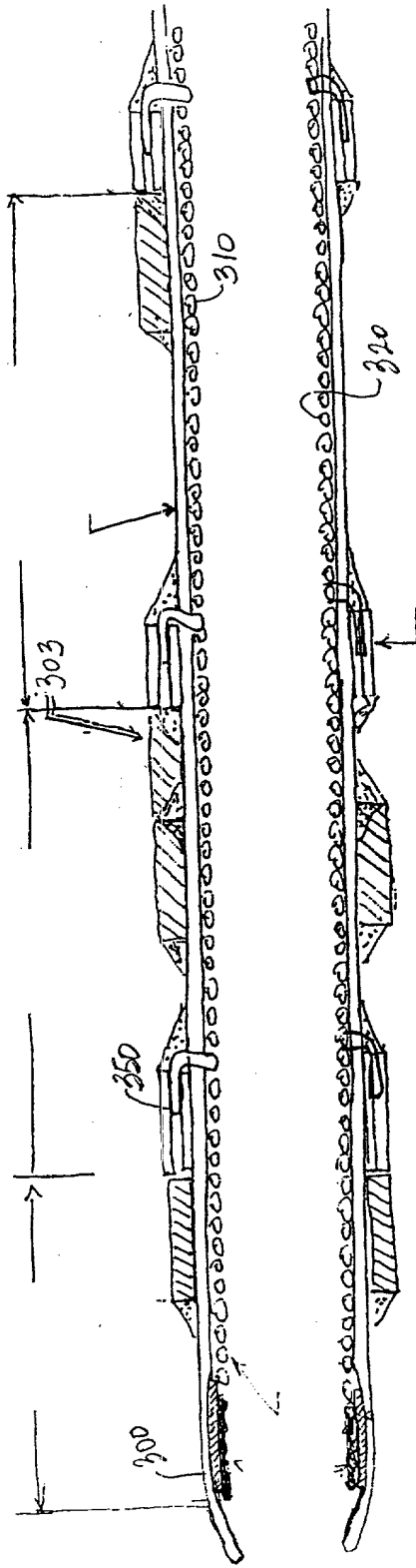


Fig. 14

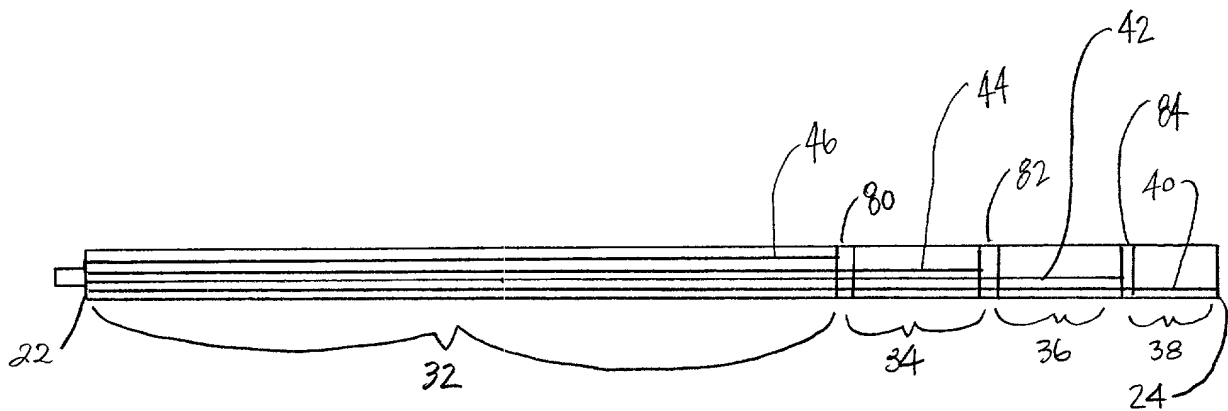


FIG. 15

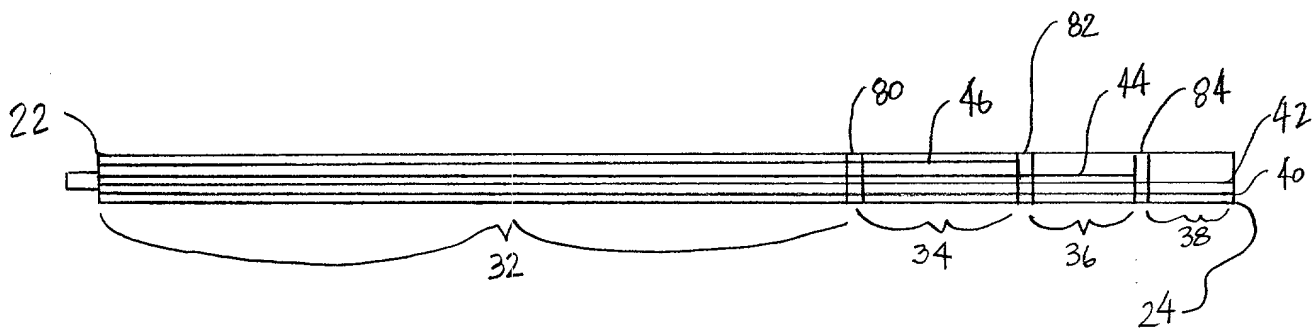


FIG. 16

SCHWEGMAN ■ LUNDBERG ■ WOESSNER ■ KLUTH

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **LEAD HAVING VARYING STIFFNESS AND METHOD OF MANUFACTURING THEREOF.**

The specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. § 1.56 (attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national or PCT international filing date in the event this is a Continuation-In-Part application in accordance with 37 C.F.R. § 1.63(e).

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 120 or 365(c) of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

No such claim for priority is being made at this time.

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

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Black, David W.	Reg. No. 42,331	Klima-Silberg, Catherine I.	Reg. No. 40,052	Padys, Danny J.	Reg. No. 35,635
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Dahl, John M.	Reg. No. 44,639	Maki, Peter C.	Reg. No. 42,832	Smith, Michael G.	Reg. No. 45,368
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Gamon, Owen J.	Reg. No. 36,143	Nama, Kash	Reg. No. 44,255	Viksnins, Ann S.	Reg. No. 37,748
Harris, Robert J.	Reg. No. 37,346	Nasiedlak, Tyler L.	Reg. No. 40,099	Woessner, Warren D.	Reg. No. 30,440
Huebsch, Joseph C.	Reg. No. 42,673				

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization/who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Schwegman, Lundberg, Woessner & Kluth, P.A. to the contrary.

Please direct all correspondence in this case to **Schwegman, Lundberg, Woessner & Kluth, P.A.** at the address indicated below:
P.O. Box 2938, Minneapolis, MN 55402
Telephone No. (612)373-6900

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Signature: _____
Bruce Tockman

Date: _____

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Residence: **Minneapolis, MN**

Signature: _____
Randy Westlund

Date: _____

☒ Additional inventors are being named on separately numbered sheets, attached hereto.

Serial No. not assigned

Filing Date: not assigned

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Gwen Crevensten

Date: _____

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Lili Liu

Date: _____

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Chris Zerby

Date: _____

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North Oaks, MN 55127**

Signature: _____

Jay A. Warren

Date: _____

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.